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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,992	09/17/2003	James C. Kennedy	067286-0275	1971
22428	7590	09/13/2006	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			RAMACHANDRAN, UMAMAHESWARI	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/663,992

Applicant(s)

KENNEDY ET AL.

Examiner

Umamaheswari Ramachandran

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

DETAILED ACTION

***Claim Rejections - 35 USC § 112(1)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabled for the treatment of genital wart by administering 5-aminolevulinic acid does not enable for any other compound that induces accumulation of protoporphyrin IX or any agent that is not a photosensitizer but induces synthesis of protoporphyrin IX. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not provide sufficient information to support that genital wart is treatable by the administration of any compound or an agent other than 5-aminolevulinic acid.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the

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breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

**(1) The nature of the invention:**

All of the rejected claims are drawn to a method of treating a genital wart, comprising administering to a patient a compound that induces accumulation of protoporphyrin IX in said wart or an agent, which is not a photosensitizer but induces synthesis of protoporphyrin IX in vivo.

**(2) Breadth of the claims:**

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The scope of the claims, which encompasses treatment of genital wart by a compound or an agent, which is not a photosensitizer, is broad.

**(3) Guidance of the Specification:**

The guidance given by the specification for the method of treating a genital wart, comprising administering to a patient a compound that induces accumulation of protoporphyrin IX in said wart or an agent, which is not a photosensitizer but induces synthesis of protoporphyrin IX in vivo is limited to 5-aminolevulinic acid (ALA).

**(4) Working Examples:**

The specification provides description for the administration of ALA and also for the detection and quantitation of parasites by ALA-induced fluorescence. Examples in the specification include long-term photodynamic endometrial

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ablation, detection or treatment of Yeast and Fungi, treatment of acne, cutaneous fungal infections etc where ALA is used as the compound or as an agent for the treatment.

**(5) The relative skill of those in the art:**

The relative skill of those in the medical treatment art is high, requiring advanced education and training.

**(6) The predictability of art:**

Despite the advanced training in the medical treatment arts, the arts are highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839 (1970). The state of the art is such that it is not possible to predict the outcome of administering any compound to induce accumulation of protoporphyrin IX or an agent, which is not a photosensitizer to induce synthesis of protoporphyrin IX in vivo.

**(7) The Quantity of Experimentation Necessary:**

In order to practice the above claimed invention, one of skill in the art would have to first envision formulation, dosage, duration, route and, in the case of human treatment, an appropriate animal model system for the claimed compound. One would then need to test the compound in the model system to determine whether or not the compound provides a method of treating a genital wart by inducing the accumulation or inducing the synthesis of protoporphyrin IX. If unsuccessful, one of skill in the art would have to envision a modification in the

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formulation, dosage, duration, route of administration etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. In order to practice the applicant's invention, it would be necessary for one to conduct the preceding experimentation for each type of compound or an agent, which is not a photosensitizer. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention of method of treating a genital wart, comprising administering to a patient a compound that induces accumulation of protoporphyrin IX in said wart or an agent, which is not a photosensitizer but induces synthesis of protoporphyrin IX in vivo is limited to 5-aminolevulinic acid (ALA).

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, a method of treating a genital wart, comprising administering to a patient a compound that induces accumulation of protoporphyrin IX in said wart or an agent, which is not a photosensitizer but induces synthesis of protoporphyrin IX of the claims is not considered to be enabled by the instant specification.

### **Conclusion**

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose

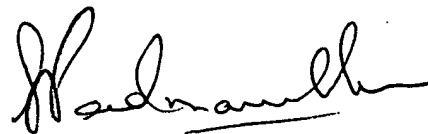
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telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER